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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,411	07/07/2005	Michael Cowley	4040.001000	6101
23579	7590	10/04/2007		
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE, SUITE 1200 1201 PEACHTREE STREET ATLANTA, GA 30361			EXAMINER MITRA, RITA	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,411	<b>Applicant(s)</b> COWLEY ET AL.	
	<b>Examiner</b> Rita Mitra	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' Preliminary Amendment filed on July 12, 2004 is acknowledged. Claims 1-27 and 30-57 have been amended. New claims 58-76 have been added. Therefore claims 1-76 are under consideration.

#### ***Election/Restriction***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-43, 51, 52, 58-76 drawn to a method for decreasing appetite, reducing hunger or sensations of hunger, increasing satiety or sensation of satiety, decreasing food intake, decreasing calorie intake, reducing nutrient availability, increasing energy expenditure, preventing, reducing or treating weight gain, inducing or promoting weight loss, maintaining a desired body weight or a desired Body Mass Index, or reducing or preventing obesity in a subject, which comprises peripherally administering a therapeutically effective amount of PYY or an agonist thereof and a therapeutically effective amount GLP-1 or an agonist thereof to the subject.

- II. Claim 44, drawn to a pharmaceutical composition comprising a therapeutically effective amount of PYY or an agonist thereof and a therapeutically effective amount GLP-1 or an agonist thereof in admixture or conjunction with a pharmaceutically suitable carrier.
- III. Claims 45-50, drawn to a pharmaceutical composition comprising a therapeutically effective amount of PYY or an agonist thereof in admixture with a pharmaceutically suitable carrier for subcutaneous administration.
- IV. Claims 53-57 drawn to a method for decreasing appetite, reducing hunger or sensations of hunger, increasing satiety or sensation of satiety, decreasing food intake, decreasing calorie intake, reducing nutrient availability, increasing energy expenditure, preventing, reducing or treating weight gain, inducing or promoting weight loss, maintaining a desired body weight or a desired Body Mass Index, or reducing or preventing obesity in a subject, which comprises peripherally administering a therapeutically effective amount of PYY or an agonist thereof to said subject.

The claims of these groups I-IV are directed to different inventions, which are not linked to form a single general concept under PCT Rule 13.1, because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

Applicants' invention, considered as a whole, lacks a special technical feature that

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defines a contribution over the prior art for example see 'X' reference in international search report, Hui et al. (WO 00/47219 A2, August 17, 2000, IDS ref.) The reference describes therapies for treating glucose metabolic disorders. The invention relates to pharmaceutical compositions of PYY therapeutics or cellular compositions, and their uses in treating and/or preventing disorders, which can be improved by altering the homeostasis of peptide hormones. In particular embodiments, the compositions of the subject methods are useful as insulinotropic agents, or to potentiate the insulinotropic effects of such molecules as GLP-1. (see page 34, lines 3-12) Therefore, the technical features of claim 1 is taught in the prior art and, thus, not considered special technical features. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

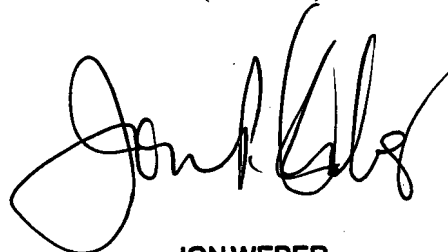
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen K. Bragdon on 571-272-0931 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

September 27, 2007



**JON WEBER  
SUPERVISORY PATENT EXAMINER**